6560-50-P

#### ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 372** 

[EPA-HQ-TRI-2012-0110; FRL-9819-1]

RIN 2025-AA34

Addition of Nonylphenol Category; Community Right-to-Know Toxic Chemical Release

Reporting

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

SUMMARY: EPA is proposing to add a nonylphenol category to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1990. EPA is proposing to add this chemical category to the EPCRA section 313 list pursuant to its authority to add chemicals and chemical categories because EPA believes this category meets the EPCRA section 313(d)(2)(C) toxicity criterion. Based on a review of the available production and use information, the members of the nonylphenol category are expected to be manufactured, processed, or otherwise used in quantities that would exceed the EPCRA section 313 reporting thresholds.

**DATES:** Comments must be received on or before [insert date 60 days after publication in the Federal Register].

**ADDRESSES:** Submit your comments, identified by Docket ID No. **EPA-HQ-TRI-2012-0110**, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Email: oei.docket@epa.gov

- Mail: Office of Environmental Information (OEI) Docket, Environmental Protection
   Agency, Mail Code: 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460
- Hand Delivery: EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301
   Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-TRI-2012-0110. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <a href="www.regulations.gov">www.regulations.gov</a> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <a href="www.regulations.gov">www.regulations.gov</a> or in hard copy at the OEI Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OEI Docket is (202) 566-1752.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Environmental Analysis Division, Office of Information Analysis and Access (2842T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-0743; fax number: 202-566-0677; email: <a href="mailto:bushman.daniel@epa.gov">bushman.daniel@epa.gov</a>, for specific information on this notice. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, toll free at (800) 424-9346 (select menu option 3) or (703) 412-9810 in Virginia and Alaska or toll free, TDD (800) 553-7672, <a href="http://www.epa.gov/superfund/contacts/infocenter/">http://www.epa.gov/superfund/contacts/infocenter/</a>.

#### **SUPPLEMENTARY INFORMATION:**

#### I. General Information

### A. Does this Notice Apply to Me?

You may be potentially affected by this action if you manufacture, process, or otherwise use nonylphenol. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities

Industry	Facilities included in the following NAICS manufacturing codes (corresponding to SIC codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 211112*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512220, 512230*, 519130*, 541712*, or 811490*.
	*Exceptions and/or limitations exist for these NAICS codes.  Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (correspond to SIC 12, Coal Mining (except 1241)); or 212221, 212222, 212231, 212234, 212299 (correspond to SIC 10, Metal Mining (except 1011, 1081, and 1094)); or 221111, 221112, 221113, 221119, 221121, 221122, 221330 (Limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (correspond to SIC 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (Limited to facilities previously classified in SIC 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC 5171, Petroleum Bulk Terminals and Plants); or 562112 (Limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (Limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 et seq.) (correspond to SIC 4953, Refuse Systems).
Federal	Federal facilities
Government	

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Some of the entities listed in the table have exemptions and/or limitations regarding coverage, and other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "FOR FURTHER INFORMATION CONTACT" section.

B. How Should I Submit CBI to the Agency?

Do not submit CBI information to EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

#### II. Introduction

Section 313 of EPCRA, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106. Congress established an initial list of toxic chemicals that comprised more than 300 chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if any of the listing criteria in Section 313(d)(2) are met. Therefore, to add a chemical, EPA must demonstrate that at least one criterion is met, but need not determine whether any other criterion is met. The EPCRA section 313(d)(2) criteria are:

(A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to

exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

- (B) The chemical is known to cause or can reasonably be anticipated to cause in humans:
  - (i) cancer or teratogenic effects, or
  - (ii) serious or irreversible-
    - (I) reproductive dysfunctions,
    - (II) neurological disorders,
    - (III) heritable genetic mutations, or
    - (IV) other chronic health effects.
- (C) The chemical is known to cause or can be reasonably anticipated to cause, because of:
  - (i) its toxicity,
  - (ii) its toxicity and persistence in the environment, or
- (iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the section 313(d)(2)(A) criterion as the "acute human health effects criterion;" the section 313(d)(2)(B) criterion as the "chronic human health effects criterion;" and the section 313(d)(2)(C) criterion as the "environmental effects criterion."

EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432) a statement clarifying its interpretation of the section 313(d)(2) and (d)(3) criteria for modifying the section 313 list of toxic chemicals.

#### **III. Background Information**

#### A. What is Nonylphenol?

Nonylphenol is an organic chemical whose main use is in the manufacture of nonylphenol ethoxylates, which are nonionic surfactants used in a wide variety of industrial applications and consumer products (Reference (Ref.) 1). Nonylphenol is persistent in the aquatic environment, moderately bioaccumulative, and extremely toxic to aquatic organisms (Ref. 1). Nonylphenol has also been detected in human breast milk, blood, and urine (Ref. 1). *B. What is the Chemical Structure and Identification of Nonylphenol?* 

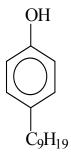
The chemical structure of nonylphenol consists of a phenol ring (benzene with a hydroxyl (OH) group) with a nonyl group (a nine carbon alkyl chain) attached to the phenol ring. The nonyl group can either be a branched or linear chain located at various positions on the phenol ring (primarily the ortho (2) and para (4) positions). Nonylphenol is not a single chemical structure. Rather it is a complex mixture of highly branched nonylphenols, mostly monosubstituted in the para position (i.e., the 4 position), with small amounts of ortho- and disubstituted nonylphenols. In addition, nonylphenol can include small amounts of branched 8 carbon and 10 carbon alkyl groups (Ref. 2).

As noted in EPA's Action Plan for nonylphenol (Ref. 1), Chemical Abstract Service Registry Numbers (CASRNs) that are routinely used for nonylphenols may not accurately reflect the identity of those substances. Manufacturers may incorrectly use a linear identity when actually referring to branched nonylphenol. CASRN 84852-15-3 corresponds to the most widely produced nonylphenol, branched 4-nonylphenol. Much of the literature refers to the linear (or normal) nonylphenol (CASRN 25154-52-3) and there are also references to a specific linear para isomer 4-n-nonylphenol (CASRN 104-40-5), which is covered within the broader CASRN 25154-52-3. Many, but not all, references may be inaccurate about the identity of the substances

listed as nonylphenol due to inaccurate identities in the source material. A supplier of nonylphenol may use CASRN 104-40-5, signifying the linear 4-n-nonylphenol, while actually supplying branched 4-nonylphenol (CASRN 84852-15-3). The name 4-nonylphenol is listed as a synonym under CASRN 104-40-5, which may lead to such confusion.

### C. How is EPA Proposing to List Nonylphenol on the TRI?

Because there is no one CASRN that adequately captures what is referred to as nonylphenol and because of the apparent confusion that has resulted from the use of multiple CASRNs, EPA is proposing to add nonylphenol as a category defined by a structure. EPA is proposing to define the nonylphenol category using the structure and text presented below.



Where  $C_9H_{19}$  = Branched or linear alkyl chain

This category definition covers the chemicals that are included in CASRNs 84852-15-3 as well as those 4 position isomers covered by CASRN 25154-52-3. Any nonylphenol that meets the above category definition would be reportable regardless of its assigned CASRN.

## IV. What Is EPA's Evaluation of the Environmental Toxicity of Nonylphenol?

Nonylphenol is toxic to aquatic organisms and has been found in ambient waters.

Because of nonylphenol's toxicity, chemical properties, and widespread use as a chemical intermediate, concerns have been raised over the potential risks to aquatic organisms from exposure to nonylphenol. All of the hazard information presented here has been adapted from

EPA's 2005 Water Quality Criteria document for nonylphenol, which was previously peer reviewed (Ref. 3).

## A. Acute Toxicity to Aquatic Animals.

1. Freshwater Species. The acute toxicity values of nonylphenol to freshwater organisms are shown in Table 1. Acute toxicities have been determined for more than 18 species representing over 15 genera. Toxicity values ranged from 21 micrograms per liter (μg/L) for a detritivorous amphipod (Hyalella aztecta) to 774 μg/L for an algal grazing snail (Physella virgata) (Ref. 4). No relationships were found between nonylphenol toxicity and water hardness or pH.

An amphipod (*Hyalella azteca*) was the most sensitive species tested with LC<sub>50</sub> values (i.e., the concentration that is lethal to 50% of test organisms) ranging from 21 to 150  $\mu$ g/L (Refs. 4 and 5). Reported EC<sub>50</sub> values (i.e., the concentration that is effective in producing a sublethal response in 50% of test organisms) for the water flea (*Daphnia magna*) ranged from 104 to 190  $\mu$ g/L in renewal and static tests respectively (Refs. 4 and 6). The overall mean acute value for *Daphnia magna* was 141  $\mu$ g/L.

Species least sensitive to nonylphenol were also invertebrates. An annelid worm (*Lumbriculus variegatus*) had an LC<sub>50</sub> of 342  $\mu$ g/L, while the acute endpoint for a dragonfly nymph (*Ophiogomphus* sp.) was an LC<sub>50</sub> of 596  $\mu$ g/L (Ref. 4). The least sensitive species tested was a snail (*Physella virgata*) with an LC<sub>50</sub> of 774  $\mu$ g/L. Eleven species of fish were tested and found to be in the mid-range of sensitivity to nonylphenol with acute values ranging from 110 to 360  $\mu$ g/L.

Table 1. Acute Toxicity of Nonylphenol to Freshwater Organisms.

Sr	oecies	Common	Method <sup>a</sup>	pН	LC <sub>50</sub> or	Reference
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	Name			EC <sub>50</sub>	
Hyalella azteca (juvenile, 2 mm total length)	Amphipod	F, M	7.80	(μg/L) 21	Ref. 4
Daphnia magna (< 24 hr old)	Water Flea	R, M	7.87	104	Ref. 4
Etheostoma rubrum (0.062g, 20.2 mm)	Fountain Darter	S, U	8.0 – 8.1	110	Ref. 7
Bufo boreas (0.012g, 9.6 mm)	Boreal Toad	S, U	7.9 – 8.0	120	Ref. 7
Pimephales promelas (25 - 35 days old)	Fathead Minnow	F, M	7.23	128	Ref. 8
Oncorhynchus mykiss $(0.27 \pm 0.07g)$	Rainbow Trout	S, U	7.9	140	Ref. 9
Oncorhynchus clarki henshawi (0.34 ± 0.08g)	Lahontan Cutthroat Trout	S, U	7.9	140	Ref. 9
Pimephales promelas (32 days old)	Fathead Minnow	F, M	7.29	140	Refs. 10 and 11
Hyalella azteca (juvenile, 2- 3mm total length)	Amphipod	F, M	7.9 – 8.7	150	Ref. 5
Oncorhynchus clarki stomais $(0.31 \pm 0.17g)$	Greenback Cutthroat Trout	S, U	7.5 – 7.6	150	Ref. 9
Chironomus tentans (2 <sup>nd</sup> instar)	Midge	F, M	8.0 – 8.4	160	Ref. 12
Oncorhynchus mykiss $(0.48 \pm 0.08g)$	Rainbow Trout	S, U	7.5 – 7.9	160	Ref. 9
Oncorhynchus apache $(0.38 \pm 0.18g)$	Apache Trout	S, U	7.3 – 7.7	160	Ref. 9
$Xy$ rauchen $texanus$ $(0.31 \pm 0.04g)$	Razorback Sucker	S, U	7.8 – 8.1	160	Ref. 9

Gila elegans $(0.29 \pm 0.08g)$	Bonytail Chub	S, U	7.7 – 7.9	270	Ref. 9
Ptychocheilus lucius (0.34 ± 0.05g)	Colorado Squawfish	S, U	7.8 – 8.0	270	Ref. 9
Pimephales promelas $(0.39 \pm 0.14g)$	Fathead Minnow	S, U	7.8 – 8.2	290	Ref. 9
Pimephales promelas $(0.45 \pm 0.35g)$	Fathead Minnow	S, U	7.6 – 7.8	310	Ref. 9
Gila elegans $(0.52 \pm 0.09g)$	Bonytail Chub	S, U	7.4 – 7.6	310	Ref. 9
Pimephales promelas $(0.40 \pm 0.21g)$	Fathead Minnow	S, U	7.5 – 7.9	330	Ref. 9
Lumbriculus variegatus (adult)	Annelid	F, M	6.75	342	Ref. 4
Pimephales promelas $(0.56 \pm 0.19g)$	Fathead Minnow	S, U	7.8 – 8.1	360	Ref. 9
Ophiogomphus sp. (nymph)	Dragonfly	F, M	8.06	596	Ref. 4
Physella virgata (adult)	Snail	F, M	7.89	774	Ref. 4

<sup>&</sup>lt;sup>a</sup> S = Static; R = Renewal; F = Flow-through; M = Measured; U = Unmeasured.

2. Saltwater Species. The acute toxicity values of nonylphenol to saltwater organisms are shown in Table 2. Acute toxicities have been determined for 11 species within 11 genera. Acute toxicity values ranged from 17 μg/L for the winter flounder (*Pleuronectes americanus*) (Ref. 13), to 310 μg/L for the sheepshead minnow (*Cyprinodon variegatus*) (Ref. 14).

A number of benthic invertebrates have been investigated including a deposit-feeding clam (*Mulinia lateralis*) with an LC<sub>50</sub> of 38  $\mu$ g/L (Ref. 13), a copepod (*Acartia tonsa*) with an LC<sub>50</sub> of 190  $\mu$ g/L (Ref. 15), the American lobster (*Homarus americanus*) with an LC<sub>50</sub> of 71  $\mu$ g/L (Ref. 13), the mud crab (*Dyspanopeus sayii*) with an LC<sub>50</sub> greater than 195  $\mu$ g/L (Ref. 13),

and two amphipods (*Leptocheirus plumulosus*) with an LC $_{50}$  of 62  $\mu$ g/L (Ref. 13) and (*Eohaustorius estuarius*) with an LC $_{50}$  of 138  $\mu$ g/L (Ref. 16).

Table 2. Acute Toxicity of Nonylphenol to Saltwater Aquatic Organisms.

Species	Common Name	Method <sup>a</sup>	рН	LC <sub>50</sub> or EC <sub>50</sub> (µg/L)	Reference
Pleuronectes americanus (48 hrs old)	Winter Flounder	S, M	7.8 – 8.2	17	Ref. 13
Mulinia lateralis (embryo/larvae)	Coot Clam	S, U	7.8 – 8.2	38	Ref. 13
Mysidopsis bahia <sup>b</sup> (< 24 hrs old)	Mysid Shrimp	F, M	7.3 – 8.2	43	Ref. 17
Palaemonetes vulgaris (48 hrs old)	Grass shrimp	F, M	7.8 – 8.2	59	Ref. 13
Americamysis bahia (< 24 hrs old)	Mysid Shrimp	F, M	7.8 – 8.2	61	Ref. 13
Leptocheirus plumosus (adult)	Amphipod	F, M	7.8 – 8.2	62	Ref. 13
Menidia beryllina (juvenile)	Inland Silversides	F, M	7.8 – 8.2	70	Ref. 13
Homarus americanus (1 <sup>st</sup> stage larvae)	American Lobster	R, U	7.8 – 8.2	71	Ref. 13
Eohaustorius estuarius (adult)	Amphipod	S, U	missing	138	Ref. 16
Cyprinodon variegatus (juvenile)	Sheepshead Minnow	F, M	7.8 – 8.2	142	Ref. 13
Acartia tonsa (10-12 days old)	Copepod	S, U	missing	190	Ref. 15
Dyspanopeus sayii (4 <sup>th</sup> and 5 <sup>th</sup> stage larvae)	Mud Crab	F, M	7.8 – 8.2	> 195	Ref. 13
Cyprinodon variegatus	Sheepshead Minnow	F, M	7.4 – 8.1	310	Ref. 14

(juvenile)

1. Freshwater Species. The chronic toxicity of nonylphenol to freshwater animals has been studied in two fish and three invertebrate species (Table 3). Of the invertebrates, a number of species of the cladoceran (water fleas) genus *Daphnia* have been extensively tested for chronic effects. Water flea (*Ceriodaphnia dubia*) neonates exhibited reproductive impairment when exposed to nonylphenol for 7 days at 202 μg/L and survival was impaired at concentrations of 377 μg/L (Ref. 18). Four to 24-hour old water fleas (*Daphnia magna*) showed a reduction in the number of young per brood over 9 days of exposure to concentrations as low as 48 μg/L. Based on this study, a chronic Lowest-Observed-Effect-Concentration (LOEC) was calculated to be 23 μg/L for effects on brood production (Ref. 19). Water fleas (*Daphnia magna*) exposed to 71 and 130 μg/L nonylphenol for 21 days exhibited declines in both growth and adult survival rates (Ref. 6). In a separate 21-day life cycle study of water fleas (*Daphnia magna*); growth, reproduction, and survival were all reduced at concentrations of 158 μg/L and above (Ref. 4).

Less than 24-hour-old midge (*Chironomus tentans*) larvae exposed to concentrations of nonylphenol from 12 to 200  $\mu$ g/L and showed significant declines in larval survival over the first 20 days of exposure. The chronic toxicity value for survival was calculated as 62  $\mu$ g/L (Ref. 20).

A 91-day life stage test was conducted with the embryos and fry of rainbow trout (*Oncorhynchus mykiss*) at concentrations from 6 to 114  $\mu$ g/L. Nearly all larvae were abnormal at the two highest exposure concentrations ( $\geq 53 \mu$ g/L) (Ref. 4). Survival was reduced at  $\geq 23 \mu$ g/L and growth measured as both change in weight and length was even more sensitive with

 $<sup>^{</sup>a}S = Static$ ; R = Renewal; F = Flow-through; M = Measured; U = Unmeasured.

<sup>&</sup>lt;sup>b</sup>Note that there has been a taxonomic name change, *Mysidopsis bahia* is now *Americamysis bahia*, the original names from the studies are used in this document to avoid any confusion. *B. Chronic Toxicity to Aquatic Animals*.

measured decreases at concentrations as low as 10  $\mu$ g/L. The chronic toxicity effect value for growth (both weight and length) was calculated as 8  $\mu$ g/L (Ref. 4).

Embryos and larvae of the fathead minnow (*Pimephales promelas*) were exposed in a 33-day early-life-stage test at nonylphenol concentrations ranging from 3 to 23 μg/L (Ref. 21). Hatching was delayed at the two highest concentrations (14 and 23 μg/L). Fathead minnow survival was reduced at concentrations of 14 μg/L and greater. The survival chronic toxicity effect value for fathead minnows was calculated to be 14 μg/L (Ref. 21).

2. Saltwater Species. Two chronic toxicity tests have been conducted with mysid shrimp (Mysidopsis bahia) (Ref. 22). The first experiment was a 28-day exposure measuring survival, growth, and reproduction. Shrimp survival was reduced by 18% on exposure to 9  $\mu$ g/L. Growth in length was the most sensitive endpoint with a 7% reduction in length for animals exposed to 7  $\mu$ g/L and No-Observed-Effect-Concentration (NOEC) and LOEC for growth responses of 4 and 7  $\mu$ g/L (Table 3).

The second experiment, a 28-day life-cycle test, examined the effect of nonylphenol on brood release and growth (Ref. 23). Growth of female mysids (*Americamysis bahia*) was reduced at concentrations at and above 28  $\mu$ g/L. Brood production was the most sensitive endpoint in this study. The average number of young per female-reproductive day was reduced at concentrations  $\geq$  15  $\mu$ g/L. The NOECs and LOECs for reproductive responses were 9 and 15  $\mu$ g/L.

Table 3. Chronic Toxicity of Nonylphenol to Aquatic Organisms (Freshwater and Saltwater).

Species	Common	Method <sup>a,b</sup>	pН	Chronic	Endpoint	Reference
	Name			Value		
				Range		
				(µg/L)		

Mysidopsis	Mysid	LC, SW	7.4 –	5	(NOEC x	Ref. 22
bahia <sup>c</sup>	Shrimp	LC, SW	8.3	3	$LOEC)^{1/2}$	101. 22
			0.5		Growth	
Oncorhynchus	Rainbow	ESL, FW	6.97	8	(NOEC x	Ref. 4
mykiss	Trout	, , , , ,			LOEC) <sup>1/2</sup>	
,					Growth	
Mysidopsis	Mysid	LC, SW	7.4 –	9	Survival	Ref. 22
bahia <sup>c</sup>	Shrimp	,	8.3			
Mysidopsis	Mysid	LC, SW	7.4 –	9	Reproduction	Ref. 22
bahia <sup>c</sup>	Shrimp		8.3			
Americamysis	Mysid	LC, SW	Missing	12	(NOEC x	Ref. 23
bahia	Shrimp				$LOEC)^{1/2}$	
					Total Number	
					of Young	
Pimephales	Fathead	ELS, FW	7.1 –	14	Delayed	Ref. 21
promelas	Minnow		8.2		Hatching;	
0 1 1	D : 1	EGI EW	6.05	22	Survival	- D C 4
Oncorhynchus	Rainbow	ESL, FW	6.97	23	Survival	Ref. 4
mykiss	Trout	LC FW	0.04	22	AIOEC	D C 10
Daphnia	Water	LC, FW	8.04	23	(NOEC x LOEC) <sup>1/2</sup>	Ref. 19
magna	Flea				Total Number	
					of Young	
Americamysis	Mysid	LC, SW	Missing	28	Growth	Ref. 23
bahia	Shrimp	LC, SW	Wilsonig	20	Growth	RC1. 23
Daphnia	Water	LC, FW	8.25	39	Number of	Ref. 6
magna	Flea	20,1 ,,	0.20	3,	Live Young	1101. 0
Oncorhynchus	Rainbow	ESL, FW	6.97	53	Abnormal	Ref. 4
mykiss	Trout	,			Development	
Chironomus	Midge	LC, FW	7.73	62	(NOEC x	Ref. 20
tentans		,			$LOEC)^{1/2}$	
					20 d Survival	
Daphnia	Water	LC, FW	8.25	71	Growth	Ref. 6
magna	Flea					
Daphnia	Water	LC, FW	8.25	130	Adult	Ref. 6
magna	Flea				Survival	
Daphnia	Water	LC, FW	8.46	158	(NOEC x	Ref. 4
magna	Flea				LOEC) <sup>1/2</sup>	
					Growth and	
					Reproduction;	
C · 1 · 1 ·	W/-4.	I C PW	0.2	202	Survival	D - C 10
Ceriodaphnia	Water	LC, FW	8.3 –	202	Reproductive	Ref. 18
dubia Cario danhuia	Flea	I.C. EW	8.6	277	Impairment	Dof 10
Ceriodaphnia	Water	LC, FW	8.3 –	377	Survival	Ref. 18
dubia	Flea	ovala: ELC =	8.6			

<sup>&</sup>lt;sup>a</sup> LC = life-cycle or partial life-cycle; ELS = early life-stage.

<sup>b</sup> FW = Freshwater, SW = Saltwater.

<sup>c</sup>Note that there has been a taxonomic name change, *Mysidopsis bahia* is now *Americamysis bahia*, the original names from the studies are used in this document to avoid any confusion.

#### C. Toxicity to Aquatic Plants.

- 1. Freshwater. Ecological toxicity data for freshwater plants was available only for single-celled planktonic green alga (Selenastrum capricornutum) (Ref. 24). Algae exposed to nonylphenol for 4 days had an EC<sub>50</sub> for effect on population growth rate of 410  $\mu$ g/L. The effect did not persist when the algae were transferred to fresh, uncontaminated, growth medium.
- 2. Saltwater. Ecological toxicity data for saltwater plants are available only for a single species of marine planktonic algae, a diatom (*Skeletonema costatum*) (Ref. 25). The EC<sub>50</sub> for nonylphenol effect on vegetative growth was 27  $\mu$ g/L.

#### D. Bioaccumulation.

1. Freshwater Species. Data on bioaccumulation of nonylphenol in freshwater organisms was limited to two species of fish, fathead minnow (*Pimephales promelas*) and bluegill (*Lepomis macrochirus*). Juvenile fathead minnows exposed to 5 and 23 μg/L nonylphenol for 27 days showed non-lipid-normalized bioconcentration factors (BCF) of 271 and 344 respectively (Ref. 26). Values which had been normalized to organism lipid content were approximately five times lower. A short-term (4-day) bioassay indicated that tissue concentrations reached steady-state within two days in both the fathead minnow and bluegill (Ref. 27). Overall, lipid-normalized BCF's for fathead minnows in 4- and 27-day tests ranged from 128 to 209 and for bluegills from 39 to 57 (Ref. 8). A 42-day exposure experiment using fathead minnows and exposure concentrations of 0.4 to 3.4 μg/L resulted in BCFs ranging from 203 to 268 (Ref. 28).

2. Saltwater Species. Bioconcentration factors are available for three species of marine animals; the blue mussel (Mytilus edulis), the three-spined stickleback fish (Gasterosteus aculeatus), and a benthic shrimp (Crangon crangon) (Ref. 29). Individuals of all three species were exposed to carbon-14 (<sup>14</sup>C)-labeled nonylphenol for 16 days and followed over a subsequent elimination period of 32 days. BCFs ranged from a measured value in benthic shrimp of 79 to an estimated value of 2,168 for the blue mussel.

E. Reproductive, Developmental, and Estrogenic Effects.

Numerous investigations have demonstrated the estrogenic activity of nonylphenol (see Refs. 30, 31, and 32 for reviews). The majority of studies have been conducted with aquatic species and effects have been demonstrated both *in vitro* and *in vivo*. While most of these studies have been conducted on fish, a number of species of invertebrates have also been examined.

- 1. Aquatic Invertebrates. Among invertebrates, estrogenic effects have been demonstrated in a marine amphipod (Corophium volutator) at 10 μg/L (Ref. 33) and larvae of a freshwater insect (Chironomus riparis) at 2,000 μg/L (Ref. 34). However, no estrogenic effects were found in a marine copepod (Tisbe battagliai) at exposure concentrations up to 55 μg/L (Ref. 35).
- 2. In Vivo Responses in Fish. The protein vitellogenin, which is produced in the liver, is a primary constituent in the yolk of the ova of oviparous vertebrate species (i.e., species producing eggs which hatch outside the body). Very little vitellogenin is produced in males and increased vitellogenin production in males is an indication of estrogenic effects. While nonylphenol has been shown to produce estrogenic effects, estimates from studies on male

rainbow trout (*Oncorhynchus mykiss*) suggest that it is 2,000 to 3,000 times less potent than natural estrogen (17 *beta*-estradiol) (Ref. 36).

Exposure to nonylphenol has been shown to increase vitellogenin production in male rainbow trout (*Oncorhynchus mykiss*) at concentrations from 10 to 100 μg/L over periods of 4 hours to 3 days (Refs. 37, 38 and 39). Jobling and colleagues (Ref. 40) also found increased vitellogenin production in male rainbow trout after 21 days of exposure to nonylphenol concentrations of 20 and 54 μg/L. Similarly, Tremblay and van der Kraak (Ref. 41) found increased plasma vitellogenin after 3 weeks of exposure to 50 μg/L nonylphenol in rainbow trout. Female rainbow trout are similarly sensitive with vitellogenin induction occurring with exposures ranging from 8 to 86 μg/L (Ref. 42). The study on female rainbow trout also noted that nonylphenol exposure caused changes in several pituitary and hormone plasma levels. Exposure to nonylphenol concentrations as low as 4 μg/L led to vitellogenin induction in male green swordfish (*Xiphophorous helleri*). In contrast, additional studies did not show vitellogenin induction in rainbow trout exposed for 9 days at 109 μg/L (Ref. 43) or the Atlantic salmon (*Salmo trutta*) exposed for 30 days to 20 μg/L (Ref. 44).

Vitellogenin messenger ribonucleic acid (mRNA) is a direct precursor to protein formation and increased production in rainbow trout at concentrations of 10 to 14  $\mu$ g/L when exposed for 4 and 72 hours respectively (Ref. 3). Increased levels of plasma vitellogenin and several pituitary and plasma hormone levels were observed in female rainbow trout exposed to 8 and 86  $\mu$ g/L nonylphenol. The route of exposure influenced vitellogenin induction in the fathead minnow with an order of magnitude greater induction when exposed via water as opposed to diet (Ref. 45).

Fish fecundity (i.e., the rate of production of young) is also affected in various ways by nonylphenol exposure (Ref. 28). Concentrations as low as 0.5 to 3.4  $\mu$ g/L, although not acutely toxic, decreased the fecundity of fathead minnows at various times over the reproductive season. At concentrations of approximately 0.1  $\mu$ g/L, fecundity was increased in fathead minnows. These results suggest a possible hormetic response of fish fecundity to nonylphenol.

A number of studies have been performed with the fish Japanese medaka (*Oryzias latipes*). Following hatch, a cohort of Japanese medaka was exposed for 28 days and monitored for the following 55 days for survival, growth, egg viability, egg production, and gonosomatic index (GSI) (Ref. 46). No effects were noted at the lowest exposure concentration of 1.93 μg/L. However, in a 3-month exposure study with the same species, effects were noted at 50 μg/L and included intersex (development of ovo-testis) and the sex ratio shifted in favor of females (Ref. 47). Another study of Japanese medaka found that, in fish exposed from fertilized egg to 60 days post-hatch, the LOEC for vitellogenin induction was found to be 12 μg/L (Ref. 48).

A two-generation (F<sub>0</sub> and F<sub>1</sub>) flow-through study exposed Japanese medaka from eggs to 60 days post-hatch of the second (F<sub>1</sub>) generation at concentrations ranging from 4 to 183 μg/L (Ref. 49). For the F<sub>0</sub> generation, egg hatchability was reduced by 48% at 187 μg/L. Survival was reduced at 60 days post-hatch for exposures at or above 18 μg/L. However, no differences in growth rates were observed in the F<sub>0</sub> generation at any exposure concentration 60 days post-hatch. Induction of ovo-testis was observed at 18 μg/L with 20% of the fish exhibiting external male characteristics having ovo-testis. At 51 μg/L, all fish exhibited external female characteristics with 40% containing ovo-testis. Spermatogenesis was observed in ovo-testis containing fish exposed to 18 but not 51 μg/L. Fecundity was not affected by nonylphenol exposure. GSI of female fish was increased by exposure to concentrations greater than 8 μg/L.

Effects of exposure on the  $F_1$  generation were also reported with no embryological abnormalities or hatching failures observed at any of the treatment concentrations. Growth was also not affected at 60 days post-hatch in the  $F_1$  generation. However, the sex ratio as determined by secondary sexual characteristics changed in favor of females (1:2) at concentrations greater than 18  $\mu$ g/L. Induction of ovo-testis occurred at lower concentrations in the  $F_1$  as opposed to the  $F_0$  generation (8 versus 18  $\mu$ g/L). All fish in the  $F_1$  generation with ovo-testis displayed external male characteristics and the degree of oocyte development was not as complete as with the  $F_0$  18  $\mu$ g/L treatment. The overall results suggest a NOEC and LOEC of approximately 8 and 18  $\mu$ g/L respectively.

A multi-generational study has also been conducted for the rainbow trout (*Oncorhynchus mykiss*) (Ref. 50). Exposure to concentrations of 1 and 10  $\mu$ g/L of adult males and females was intermittent over 4 months. Vitellogenin induction was increased in adult male fish exposed to both 1 and 10  $\mu$ g/L. Male progeny of fish exposed to 10  $\mu$ g/L showed elevated plasma estradiol concentrations. Female progeny showed elevated levels of plasma testosterone and vitellogenin concentrations.

#### V. Rationale for listing

EPA's technical evaluation of nonylphenol shows that it can reasonably be anticipated to cause, because of its toxicity, significant adverse effects in aquatic organisms. Toxicity values for nonylphenol are available for numerous species of aquatic organisms. The observed effects from nonylphenol exposure occur at very low concentrations demonstrating that nonylphenol is highly toxic to aquatic organisms. Data summarized in this document include acute toxicity values for freshwater organisms ranging from 21  $\mu$ g/L for a detritivorous amphipod to 774  $\mu$ g/L for an algal grazing snail. Acute toxicity values for freshwater fish ranged from 110  $\mu$ g/L for the

fountain darter to 128 to 360  $\mu$ g/L for the fathead minnow. Acute toxicity values for saltwater organisms ranged from 17  $\mu$ g/L for the winter flounder to 310  $\mu$ g/L for the sheepshead minnow. Chronic toxicity values are also available for several aquatic species ranging from 5  $\mu$ g/L for growth effects in mysid shrimp to 377  $\mu$ g/L for survival effects in water fleas. Chronic toxicity values for rainbow trout ranged from 8  $\mu$ g/L for effects on growth to 53  $\mu$ g/L for abnormal development. Reproductive, developmental, and estrogenic effects on aquatic organisms have also been reported for nonylphenol with some effects observed at concentrations of 4  $\mu$ g/L or less. Therefore, EPA believes that the evidence is sufficient for listing the nonylphenol category on the EPCRA section 313 toxic chemical list pursuant to EPCRA section 313(d)(2)(C) based on the available ecological toxicity data.

EPA does not believe that it is appropriate to consider exposure for chemicals that are highly toxic based on a hazard assessment when determining if a chemical can be added for environmental effects pursuant to EPCRA section 313(d)(2)(C) (see 59 FR 61440-61442). Therefore, in accordance with EPA's standard policy on the use of exposure assessments (59 FR 61432), EPA does not believe that an exposure assessment is necessary or appropriate for determining whether the nonylphenol category meets the criteria of EPCRA section 313(d)(2)(C).

#### VI. References

EPA has established an official public docket for this action under Docket ID No. EPA-HQ-TRI-2012-0110. The public docket includes information considered by EPA in developing this action, including the documents listed below, which are electronically or physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents

are electronically or physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not electronically or physically located in the docket, please consult the person listed in the above FOR FURTHER INFORMATION CONTACT section.

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## VII. What are the Statutory and Executive Order Reviews Associated With This Action?

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This proposed rule does not contain any new information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et. seq. Currently, the facilities subject to the reporting requirements under EPCRA 313 and PPA 6607 may use either the EPA Toxic Chemicals Release Inventory Form R (EPA Form 9350-1), or the EPA Toxic Chemicals Release Inventory Form A (EPA Form 9350-2). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria. For the Form A, EPA established an alternative threshold for facilities with low annual reportable amounts of a listed toxic chemical. A facility that meets the appropriate reporting thresholds, but estimates that the total annual reportable amount of the chemical does not exceed 500 pounds per year, can take advantage of an alternative manufacture, process, or otherwise use threshold of 1 million pounds per year of the chemical, provided that certain conditions are met, and submit the Form A instead of the Form R. In addition, respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322 42 U.S.C. 11042: 40 CFR part 350.

OMB has approved the reporting and recordkeeping requirements related to Forms A and R, supplier notification, and petitions under OMB Control number 2025-0009 (EPA Information Collection Request (ICR) No. 1363) and those related to trade secret designations under OMB Control 2050-0078 (EPA ICR No. 1428). As provided in 5 CFR 1320.5(b) and 1320.6(a), an Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers relevant to EPA's regulations are listed in 40 CFR part 9, 48 CFR chapter 15, and displayed on the information collection instruments (e.g., forms, instructions).

For the 57 Form Rs and 13 Form As expected to be filed, EPA estimates the industry reporting and recordkeeping burden for collecting this information to average, in the first year, \$246,429 (based on 4,874 total burden hours) (Ref. 51). In subsequent years, the burden for collecting this information is estimated to average \$117,350 (based on 2,321 total burden hours). These estimates include the time needed to become familiar with the requirement (first-year only); review instructions; search existing data sources; gather and maintain the data needed; complete and review the collection information; and transmit or otherwise disclose the information. The actual burden on any facility may be different from this estimate depending on the complexity of the facility's operations and the profile of the releases at the facility. Upon promulgation of a final rule, the Agency may determine that the existing burden estimates in the ICRs need to be amended in order to account for an increase in burden associated with the final action. If so, the Agency will submit an information collection worksheet (ICW) to OMB requesting that the total burden in each ICR be amended, as appropriate.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A business that is classified as a "small business" by the Small Business Administration at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or

special district with a population of less than 50,000; and (3) a small organization that is any notfor-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Of the 70 entities estimated to be impacted by this proposed rule, 34 are small businesses. Of the affected small businesses, all 34 are projected to have cost-to-revenue impacts of less than 1% in both the first and subsequent years of the rulemaking. Facilities eligible to use Form A (those meeting the appropriate activity threshold which have 500 pounds per year or less of reportable amounts of the chemical) will have a lower burden. No small governments or small organizations are expected to be affected by this action. Thus this rule is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is located in EPA's economic analysis support document (Ref. 51). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

## D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA's economic analysis indicates that the total cost of this rule is estimated to be \$246,722 in the first year of reporting. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small

governments. Small governments are not subject to the EPCRA section 313 reporting requirements.

#### E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Indian Tribal Governments, EPA specifically solicits additional comment on this proposed action from tribal officials.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under

section 5-501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by

identifying and addressing, as appropriate, disproportionately high and adverse human health or

environmental effects of their programs, policies, and activities on minority populations and low-

income populations in the United States. EPA has determined that this proposed rule will not

have disproportionately high and adverse human health or environmental effects on minority or

low-income populations because it does not affect the level of protection provided to human

health or the environment. This proposed rule adds an additional chemical to the EPCRA section

313 reporting requirements. By adding a chemical to the list of toxic chemicals subject to

reporting under section 313 of EPCRA, EPA would be providing communities across the United

States (including minority populations and low income populations) with access to data which

they may use to seek lower exposures and consequently reductions in chemical risks for

themselves and their children. This information can also be used by government agencies and

others to identify potential problems, set priorities, and take appropriate steps to reduce any

potential risks to human health and the environment. Therefore, the informational benefits of the

proposed rule will have a positive impact on the human health and environmental impacts of

minority populations, low-income populations, and children.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping

requirements, and Toxic chemicals

Dated: June 14, 2013.

Bob Perciasepe,

Acting Administrator.

Therefore, it is proposed that 40 CFR part 372 be amended as follows:

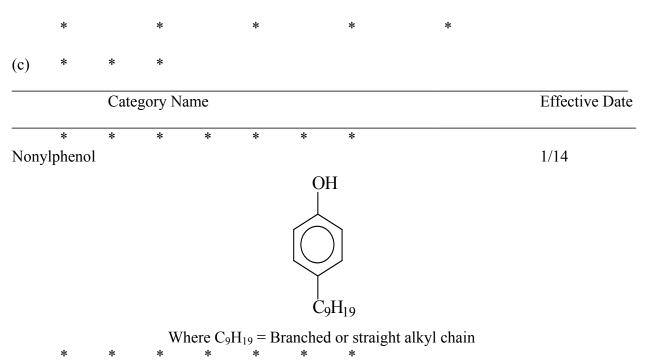
# PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

2. The table in § 372.65 paragraph (c) is amended by adding an entry in alphabetical order for "Nonylphenol" to read as follows:

# § 372.65 Chemicals and chemical categories to which the part applies.



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